# <u>REMARKS</u>

#### Status of the Claims

Claims 1-5, 7-10, 12-22, 25-27, 29-32 and 34-45 are pending; claims 16 and 44-45 are withdrawn; claims 1, 3-4, 7-9, 13-15, 20-22, 29, 32, 34-36 and 40-43 are amended; claims 6, 11, 23-24, 28 and 33 are canceled; and new claims 46 and 47 are added.

Claims 1 and 29 have been amended to recite that the administration of the antibody is carried out within 4 hours of performing surgery, during surgery or both. Support for this amendment is found, for instance, in original claim 4.

Claims 1 and 29 have also been amended to recite that immunocomplexing activates an antibody-dependent cellular cytotoxicity effector function and a complement dependent cytotoxicity effector function. Support for this amendment is found, for instance, in original claim 6.

Claims 14, 15 and 40 have been amended to recite that immune complexes of the antibody and tumor tissues or cells in blood or serum samples are determined after the surgical intervention. Support for this amendment is found, for instance, in the second paragraph of page 9 of the specification.

Claims 20-22 have been amended to correct their dependencies from claim 8 to claim 9.

Claims 3, 7-9, 13, 34-36 and 41-43 have been amended to improve grammar.

New claims 46 and 47 depend from claims 1 and 29, respectively, and recite that the antibody is a chimeric antibody and/or a humanized antibody. Support for these claims is found, for instance, in original claim 8.

No new matter has been added.

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## 1. Objections to the Claims

The Examiner has objected to claims 1, 3-4, 11, 17, 20-22, 26, 28 and 30-32 for a series of informalities listed on pages 8-9 of the Office Action. Applicants have amended or canceled these claims as described above, thereby obviating the objections.

## 2. Claim Rejections under 35 USC Section 112, Second Paragraph

The Examiner has rejected claims 6-9, 11, 13-15, 18-22, 34-36 and 40-43 as allegedly indefinite. (Office Action, pages 10-13). Applicants respectfully traverse.

Applicants have amended or canceled these claims as described above, thereby obviating these rejections.

## 3. Claim Rejections under 35 USC Section 112, First Paragraph-Written Description

The Examiner has rejected claims 22 and 43 as allegedly containing new matter. Applicants have amended these claims to correct the typographical error "2 mg" to "2 g." Support for this amendment is found, for instance in original claim 9. Accordingly, the new matter rejection is overcome.

### 4. Claim Rejections under 35 USC Section 102

#### 4.1 Goldenberg et al.

The Examiner has rejected claims 1-8, 10-15, 18-19 and 22 as allegedly anticipated by USPN 5,716,595 to Goldenberg et al., as evidenced by Abbas et al. (1991).

Solely to expedite prosecution, Applicants have amended claims 1 and 29 to specify that the antibody is administered within 4 hours of performing surgery, during surgery or both. In contrast, Goldenberg et al. teaches administering tumor-specific, fluorescently-labeled antibodies to cancer patients at least eight hours prior to surgery for detecting tumors during

surgery. Applicants emphasize that the Goldenberg et al. methods require removal of the background fluorescence caused by non-specifically bound antibodies (*i.e.* antibodies not bound to tumor tissue) by at least eight hours of systemic circulation prior to surgery. Accordingly, Goldenberg et al. does not anticipate the presently claimed tumor treatment methods, in which antibody is administered within 4 hours of performing surgery, during surgery or both. Applicants therefore respectfully request reconsideration and withdrawal of the instant anticipation rejection. Applicants also maintain their right to pursue the broader claims in a divisional/continuation application

#### 4.2 Ferrari et al.

The Examiner has rejected claims 1-8, 10-15 and 18-19 as allegedly anticipated by USPN 6,107,102 to Ferrari et al., as evidenced by a Abbas et al. (1991).

Applicants have amended claims 1 and 29 to specify that immunocomplexing activates an antibody-dependent cellular cytotoxicity effector function and a complement dependent cytotoxicity effector function. In contrast, Ferrari et al. relates to 50 nm - 3 µm microdevices, the surface of which may be conjugated to antibodies in order to deliver active substances transported by the microdevices to certain targeted cells, including tumor cells. (Ferrari et al., column 5, lines 25-28; column 6, lines 44-53; column 15, line 65 to column 16, line 13; column 18, starting from line 20). Applicants submit that antibodies bound to such microdevices cannot have an antibody-dependent cellular cytotoxicity effector function or a complement dependent cytotoxicity effector function, as presently claimed. It follows that Ferrari et al. does not anticipate the presently claimed tumor treatment methods, and Applicants respectfully request reconsideration and withdrawal of the instant anticipation rejection.

## 4.3 Golub et al.

The Examiner has rejected claims 1-15 and 18-22 as allegedly anticipated by USPN 6,949,342, to Golub et al. Applicants respectfully traverse.

Applicants point out that the priority date of the present application is August 12, 2002. So the

priority date for the present application antedates the December 19, 2002 filing date of the Golub et al. U.S. utility patent application, but not the Galub et al. priority date established by U.S. Provisional Application No. 60/343,448, filed on December 21, 2001.

U.S. Provisional Application No. 60/343,448, however, fails to describe the use of marker-specific antibodies during a surgical intervention. (See U.S. 60/343,448, a copy of which is enclosed with this paper). So Galub et al. does not anticipate the presently claimed tumor treatment methods, and Applicants respectfully request reconsideration and withdrawal of the instant anticipation rejection.

# 5. Claim Rejections under 35 USC Section 103

The Examiner has imposed a series of obviousness rejections in which Goldenberg et al., Galub et al. and Ferrari et al. are the primary references references. (Office Action, pages 19-26). Applicants respectfully traverse.

For the reasons set forth above in the anticipation section, the primary references in the obviousness rejections all fail to teach a tumor treatment method in which antibodies that have an antibody-dependent cellular cytotoxicity effector function and a complement dependent cytotoxicity effector function are administered within 4 hours of performing surgery, during surgery or both, as currently claimed. Because the secondary prior art references cited by the Examiner in the obviousness rejections fail to rescue these deficiencies in the teachings of the primary references, none of the various combinations of prior art references cited in the obviousness rejections teach the presently claimed tumor treatment methods. It follows that the Examiner has failed to establish *prima facie* obviousness, and Applicants respectfully request reconsideration and withdrawal of all obviousness rejections.

## 6. The Double Patenting Rejections

On pages 27-29 of the Office Action, the Examiner has imposed a series of claim rejections on the grounds of obviousness-type double patenting. Applicants respectfully submit that this rejection will be addressed upon a finding of patentable subject matter in the present

application.

### 7. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request immediate allowance of this application, the claims of which define subject matter that meet all statutory patentability requirements.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson, Registration No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: January 14, 2008

Respectfully submitted,

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Attachments:

U.S. 60/343,448